In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1179V

Filed: March 11, 2020

MAUREEN C. CLAVIO,	*	UNPUBLISHED
Petitioner,	*	
v.	*	Fact Ruling on the Record; Findings of Fact and Conclusions of Law; Onset
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Ruling; Influenza ("Flu") Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA")
Respondent.	*	

Leah Durant, Esq., Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Debra Begley, Esq., U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACTS AND RULING ON ONSET[1]

Roth, Special Master:

On August 31, 2017, Maureen Clavio ("Ms. Clavio") filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program.[2] The petition alleges that Ms. Clavio received a tetanus ("Tdap") vaccination on February 2, 2012, and "[o]ver the next 24-48 hours, Ms. Clavio's arm and shoulder near the vaccine site became swollen and painful…". *See* Petition at ¶¶1, 2, ECF No. 1. The petition further alleges that her injury persisted in excess of six months. *Id*. at ¶10.

[1] Although this Ruling has been formally designated "unpublished," it will nevertheless be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id*.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Background

A. Procedural History

The petition was filed on August 31, 2017. ECF No. 1. Petitioner originally filed her petition *pro se*; Ms. Durant was substituted in as counsel on August 30, 2018. *See* ECF No. 25.

This matter was assigned to me on September 5, 2017. ECF No. 4. An Order was issued that same day encouraging petitioner to seek counsel; a list of attorneys licensed to practice in the Vaccine Program was enclosed. ECF No. 5.

On September 8, 2017, petitioner filed medical records from her orthopedist, chiropractor, primary care provider, neurologist, and dentist. *See* Pet. Ex. 1-6, ECF No. 7. She also filed a letter from Dr. Boll, dated May 18, 2017, in which he stated that he recalled her having complained of shoulder pain beginning 24 to 48 hours after vaccination. Pet. Ex. 7, ECF No. 7. Dr. Boll stated that he did not have petitioner's medical records when he wrote the letter and could not verify the facts or dates as to what he wrote. *Id*. A statement from petitioner was filed as Pet. Ex. 8. ECF No. 7.

A recorded status conference was held on November 1, 2017. An in-depth conversation was had with petitioner regarding the medical records that she filed in support of her petition. Scheduling Order at 1, ECF No. 10. It was noted that, although petitioner alleges that she had pain immediately following receipt of the Tdap vaccination, this history was not supported by her records. *Id*. It was emphasized to petitioner that contemporaneous medical records are given greater weight in the Vaccine Program. *Id*. at 2. The requirement for injuries to last in excess of six months was also discussed. *Id*. Petitioner was encouraged to file additional medical records, particularly any records documenting care or treatment of her left shoulder. *Id*.

On November 7, 2017, petitioner filed letters from two co-workers at Carl Sandberg High School, David Kreis, the school's athletic trainer, and Nancy Cassidy, the school nurse. Pet. Ex. 8-9, ECF No. 11.[3] On December 12, 2017, petitioner filed letters from her mother, Florine Martin, and her husband, Wayne Clavio. Pet. Ex. 10-11, ECF No. 12. On December 29, 2017, petitioner filed letters from a former co-worker, Yolanda Kolliniatis, and a friend, Jeannie Murawski. Pet. Ex. 12-13, ECF No. 13.

On January 1, 2018, the Court issued an order for respondent to file a status report indicating how he would like to proceed in this matter. Status Report ("S.R.") Order, ECF No. 14.

Respondent filed a status report on April 9, 2018, stating that he would continue to defend this case and proposing to file a Rule 4(c) Report in 45 days. Resp. S.R. at 1, ECF No. 17. Respondent also requested that petitioner file all records from petitioner's primary care physician for the two years prior to petitioner's Tdap vaccination on February 2, 2012, and all medical

[3] Both petitioner's statement and Mr. Kreis's statement were filed as Pet. Ex. 8. In his Rule 4(c) Report, respondent referenced petitioner's statement as Pet. Ex. 8 and Mr. Kreis's statement as Pet. Ex. 8.2 to avoid confusion. *See* Rule 4 Rpt. at 9, n.11. Petitioner adopted these citations for her Motion. See Motion at 5, n.1. For continuity purposes, I will adopt these citations as well.

records pertaining to petitioner's left shoulder and right arm pain between June 29, 2012 and February 11, 2013. *Id*.

An order was issued on April 11, 2018, for petitioner to file the records requested by respondent by May 11, 2018. Scheduling Order at 2, ECF No. 18. Respondent was ordered to file his Rule 4(c) Report by June 1, 2018. *Id*. On May 10, 2018, petitioner contacted my chambers via telephone to request an extension of time to file her medical records. *See* Informal Communication, dated May 10, 2018. Petitioner was ordered to file her medical records or a status report by June 1, 2018. Scheduling Order at 1, ECF No. 20. Respondent was ordered to file his Rule 4(c) Report by July 2, 2018. *Id*.

Petitioner filed additional primary care records on June 6, 2018. Pet. Ex. 14, ECF No. 21.

Respondent filed his Rule 4(c) Report on June 28, 2018. Resp. Report, ECF No. 22. Respondent submitted that petitioner's alleged injury did not fit the criteria for SIRVA because petitioner did not provide evidence that her pain began within 48 hours of vaccination and her pain and reduced range of motion were not limited to her left shoulder. *Id*. at 12. Respondent pointed out that, based on the medical records, petitioner first reported left shoulder pain on June 13, 2012, four months post-vaccination. *Id*. at 3, 13. Respondent further noted that multiple medical records indicate that petitioner reported pain in her temple and neck in addition to her left shoulder. *Id*. at 14. Moreover, petitioner retained full range of motion in her left shoulder. *Id*.

A recorded status conference was held on July 31, 2018. During the conference, petitioner advised that she had not hired an attorney but was receiving filing and strategy assistance from a vaccine attorney. S.R. Order at 1, ECF No. 24. The issue of onset in this matter was once again discussed. *Id*. at 1-2. Petitioner was advised that there was nothing in the medical records to support an onset of her left shoulder pain prior to April 2012. *Id*. It was noted that petitioner and her doctors consistently placed the onset of shoulder pain in April 2012, two months post-vaccination. *Id*. It was further noted that petitioner did not complain of left shoulder pain when she presented to Dr. Boll's office on February 29, 2012, 25 days after receiving the Tdap vaccine. *Id*. at 2. Petitioner was advised that contemporaneous medical records are typically given more weight than allegations made years later. *Id*. Petitioner was further advised of various ways to exit the Vaccine Program. *Id*.

Leah Durant substituted in as counsel on August 30, 2018. ECF No. 25. That same day, petitioner filed a status report advising the Court that she intended to file a Motion for a Ruling on the Record. ECF No. 27. Petitioner requested 60 days to file her Motion. *Id.* An Order was issued for petitioner to file a Motion for Ruling on the Record by November 9, 2018. Non-PDF Order, issued Sept. 10, 2018. Petitioner requested and received two extensions of time. *See* Unopposed Motion for Extension of Time, ECF No. 29; Non-PDF Order, issued Nov. 13, 2018; Unopposed Motion for Extension of Time, ECF No. 30; Non-PDF Order, issued Dec. 3, 2018.

On December 3, 2018, Petitioner filed a Motion for a Ruling on the Record ("Motion") "as to the issue of onset." Motion at 1, ECF No. 31. Petitioner submitted that the onset of her injury occurred within 48 hours of vaccination. She further submitted that she met the criteria for a Table SIRVA and is entitled to vaccine compensation. *Id*. at 4-5.

Respondent requested and received two extensions of time to file his response. Unopposed Motion for Extension of Time, ECF No. 32; Non-PDF Order, issued Dec. 18, 2018; Unopposed Motion for Extension of Time, ECF No. 33; Non-PDF Order, issued Feb. 27, 2019. On April 15, 2019, respondent filed a response ("Response") to petitioner's Motion. ECF No. 34. Respondent submitted that petitioner has not provided preponderant evidence that her symptoms began within 48 hours of vaccination and therefore, petitioner does not qualify for an on-Table claim because she does not meet the QAI criteria for a SIRVA claim. Response at 1, 8. More specifically, respondent asserted that the onset of petitioner's symptoms began "no sooner than mid-April 2012, over two months after her Tdap vaccination," based on petitioner's presentation to Dr. Boll on June 13, 2012, complaining of left shoulder pain for two months. *Id*. at 1.

Petitioner filed a reply ("Reply") on June 13, 2019 in which she responded to respondent's arguments regarding the onset of her alleged vaccine injury. ECF No. 38.

This matter is now ripe for determination.

B. Summary of Relevant Medical Records

Petitioner's medical history is significant for complaints related to her hips and knees. *See* Pet. Ex. 2 at 5-9; Pet. Ex. 4 at 38-39, 84. She also took Crestor for high cholesterol. *See* Pet. Ex. 14 at 25-27.

Petitioner received a Tdap vaccine on February 2, 2012, at the office of her primary care physician, Dr. Boll. Pet. Ex. 1 at 1; Pet. Ex. 4 at 10; Pet. Ex. 14 at 5.

On February 27, 2012, petitioner presented to Maya Karam, a nurse practitioner at Dr. Boll's office, with complaints of nasal congestion, sore throat, non-productive cough, ear pain, and pain on the left side of her face and teeth. Pet. Ex. 4 at 13, 15; Pet. Ex. 14 at 6. She was diagnosed with sinusitis and prescribed an antibiotic. *Id*. at 14; Pet. Ex. 14 at 7. There was no mention of any shoulder pain made at that appointment.

On May 3, 2012, petitioner faxed the results of bloodwork performed by her employer to Dr. Boll. Pet. Ex. 4 at 72; Pet. Ex. 14 at 9. Petitioner asked Dr. Boll to call her to discuss her red blood cell distribution levels, iron count, and carbon dioxide levels. *Id*.

On May 10, 2012, petitioner presented to her dentist, Dr. Corski, for temporomandibular joint ("TMJ") pain. Pet. Ex. 6 at 1. She was prescribed Flexeril and Motrin. *Id*. Petitioner returned to Dr. Corski on May 23, 2012, for hand scale polishing. *Id*. She complained of left-sided TMJ which was very tender to the touch. *Id*.

Petitioner returned to Dr. Boll's office on June 13, 2012 with complaints of left shoulder pain and left-sided temporal pain for two months. Pet. Ex. 4 at 9; Pet. Ex. 14 at 12. She also had a headache that was mild to moderate with no relief from Advil or Flexeril prescribed by her dentist. Pet. Ex. 4 at 9. She complained of difficulty raising her left arm. *Id*. She had no weakness and only mild associated posterior left neck pain. *Id*. Upon exam, petitioner had full range of motion of the cervical spine and full range of motion of the left shoulder with some pain posteriorly. *Id*. at 12;

Pet. Ex. 14 at 14. Dr. Boll suspected tendonitis leading to compensatory neck muscle pain. *Id*. He referred her for a physical therapy evaluation. *Id*.

On June 18, 2012, petitioner presented to an orthopedist, Dr. Regan, with complaints of left temple pain down into her shoulder with "spontaneous onset." Pet. Ex. 2 at 3. Upon exam, petitioner had no tenderness around her shoulder, full range of motion, good circulation, good sensation, and good motor function to her arm and hand. *Id*. An x-ray was "unremarkable." *Id*. Dr. Regan's impression was "[n]ot sure this correlates well with a shoulder problem, but it is peculiar that this radiates from her shoulder up to her temple area." *Id*. She was advised to see a neurologist. *Id*.

A record signed by Dr. Regan[4] bearing "6-2012" as the date of service noted a telephone call from petitioner: "The patient called back and talked with me today and she wants it mentioned in the chart that she may be ALLERGIC TO TETANUS-DIPHTHERIA-PERTUSSIS injection, so we will make sure that in the future we do not give her any of those injections, but we do not do that at this office." Pet. Ex. 7 at 2 (emphasis in original).

On June 29, 2012, petitioner presented to Dr. Mayer, a neurologist, complaining of head pain that radiated down to her shoulder. Pet. Ex. 5 at 10; Pet. Ex. 4 at 32; Pet. Ex. 14 at 15. She described pain over the left temple, left neck, and left shoulder. Pet. Ex. 5 at 10. Petitioner reported that the pain started in her left neck or temple "around Easter time in April" and later became associated with pain in her left shoulder. *Id*. Dr. Mayer noted that petitioner felt that all three areas of pain were related. *Id*. Petitioner reported that the pain was present "to some degree on a daily basis, but can be relatively mild at times." *Id*. She was noted to have not lost any function, had "recently hiked up a mountain in Colorado" and continued to golf. *Id*. She did not have any associated nausea or vomiting or weakness in her arm. *Id*. An x-ray of her left shoulder was unremarkable. *Id*. Upon exam, petitioner had a normal range of motion with pain on abduction and external rotation of the left shoulder which radiated to her temple. *Id*. at 11; Pet. Ex. 4 at 33; Pet. Ex. 14 at 16. X-rays of her cervical spine showed lordosis in the neck, possibly due to muscle spasm and slight disc narrowing at C3-4 but no other significant findings. Pet. Ex. 5 at 12; Pet. Ex. 4 at 34; Pet. Ex. 14 at 17. Dr. Mayer's assessment was neck strain which was mainly muscular and involved the trapezius and temporalis muscles. Pet. Ex. 5 at 12. She was prescribed gabapentin and instructed to follow-up in four to six weeks. *Id*.; Pet. Ex. 4 at 34-35; Pet. Ex. 14 at 17-18.

Petitioner did not show up for her follow-up visit with Dr. Mayer that was scheduled for August 7, 2012. Pet. Ex. 5 at 3-4.

Petitioner did not show up for a dental cleaning scheduled for October 8, 2012. Pet. Ex. 6 at 1. She presented to Dr. Corski on October 27, 2012. He noted that she was very jumpy and sensitive, making scaling difficult. *Id*. at 1-2. He encouraged flossing. *Id*.

On October 27, 2012, petitioner presented to Dr. Boll's office for a flu vaccine. Pet. Ex. 14 at 19. She received a flu vaccine in her left arm. Pet. Ex. 4 at 7.

[4] This record was not filed with the other records from Dr. Regan's office (Pet. Ex. 2). Rather, this record was filed with the letter from Dr. Boll as Pet. Ex. 7.

On November 21, 2012, petitioner underwent a treadmill stress echocardiogram. Pet. Ex. 14 at 20. It was a normal treadmill exercise study; petitioner achieved her target heart rate and did not have any arrhythmias. *Id*.

There are no further records of any medical treatment or visits until February 11, 2013, when petitioner presented to a chiropractor, Dr. Cleofe, with complaints of pain in her left arm, neck, and temple area, and pain from her left hip to the knee. Pet. Ex. 3 at 4. She described the pain in her shoulder, neck, and temple as aching and stiffness, while the pain in her hip and knee was characterized as "sharp." *Id*. Petitioner reported that in April 2012, she woke up with pain in her left temple; she later noticed it in her left arm and her neck, and it was progressing to her right upper arm as well. *Id*. at 11. She had not missed any work due to her symptoms and reported that they affected her life "mildly," but she did have difficulty donning and doffing shirts and coats. *Id*. at 1, 2, 7. Her condition had become worse since October of 2012. *Id*. at 11. She described feeling "achy all over," like she was "getting old and falling apart…". *Id*. at 1. Upon exam, she had pain with left shoulder abduction. *Id*. at 2. Cervical spine x-rays were performed and showed degenerative disc disease from C3 to C6. *Id*. at 22. The soft tissue structures were unremarkable and there was no evidence of joint pathology. *Id*. When asked about possible precipitating events, petitioner stated she had a Tdap vaccination in her left shoulder in April 2012, one day before all the pain began. *Id*. at 2, 11. Dr. Cleofe questioned whether petitioner had a gradual, insidious onset of rotator cuff disease. *Id*. at 1. He recommended an eight-week course of treatment involving myofascial release therapy, shoulder rehabilitation protocols, and TMJ soft tissue therapy. *Id*. at 2.

Petitioner returned for chiropractic treatment on February 15, 18, 20, 22, 25, and 27, 2013. *See* Pet. Ex. 3 at 26-31. She continued treatment through March 2013 and appeared to have some improvement; on March 8, 2013, petitioner reported that she was "feeling really good." Pet. Ex. 3 at 32-35. A few days later, on March 11, 2018, petitioner reported that she did some climbing in the crawl space of her home and irritated her left shoulder. *Id*. at 36. She continued to present regularly through March for care. *Id*. at 37-43.

On April 2, 2013, petitioner presented to Dr. Boll complaining of nasal congestion, ear pain, and sinus pressure. Pet. Ex. 4 at 6. She was diagnosed with acute sinusitis and prescribed amoxicillin. *Id*. at 8. The record does not reflect any complaints of shoulder pain.

Petitioner continued to present for chiropractic care through April 2013. Pet. Ex. 3 at 45-54. On April 22, 2013, petitioner reported that she was having left jaw pain which began in April 2012, "about the same time when L shoulder pain came about." *Id*. at 53. Her left arm and shoulder pain were improving, and she wished to continue treatment for her left shoulder. *Id*. She returned regularly for treatment through May and June 2013. *Id*. at 55-66. During an appointment on June 5, 2013, Dr. Cleofe noted that petitioner's left shoulder was improving and less painful; petitioner reported that she was able to swing a golf club. *Id*. at 61. On July 29, 2013, Dr. Cleofe wrote that petitioner had discontinued treatment but returned, reporting that "she may have exacerbated her condition after doing planks a few months ago." *Id*. at 67. She also reported some pain after 18 holes of golf. *Id*. at 68. Dr. Cleofe recommended an eight-week treatment plan. *Id*. at 67.

An MRI of petitioner's left shoulder was performed on August 21, 2013 and revealed "minimal heterogeneous change within the supraspinatus tendon" with no evidence of tear of any

rotator cuff tendons. Pet. Ex. 3 at 23. The impression was "[t]endinopathy…within the supraspinatus tendon." *Id*. at 24.

Petitioner regularly presented for chiropractic care through August, September, and October of 2013. *See* Pet. Ex. 3 at 67-88. At an appointment on November 22, 2013, petitioner reported to Dr. Cleofe that she had not been doing her shoulder exercises, and had reaggravated her left shoulder one week earlier, when she reached to catch something and felt severe pain in her left shoulder. *Id*. at 89. Petitioner continued to receive chiropractic care through 2017. *See id*. at 90-189.

The remainder of petitioner's medical records are not relevant to the issue of onset.

C. Statements Prepared for Litigation

1. Petitioner

Petitioner submitted a letter dated April 2015 but signed and notarized on August 7, 2017. Pet. Ex. 8 at 2, 6. Petitioner stated, "…from the moment the [Tdap] shot was given I was experiencing pain at the injection site." *Id*. at 2. She stated that within 24 to 48 hours of receiving the Tdap vaccination, she called Dr. Boll's office to speak with him or a nurse about her symptoms and was advised to use over the counter medication and ice. *Id*. Petitioner explained that she has experienced pain with injections in the past, so she "just assumed that this was a normal thing when getting a shot." *Id*. Petitioner stated that she continued to experience pain and it began to radiate from her shoulder to her neck and jaw. *Id*. She stated that she had difficulty making an appointment due to working full-time. *Id*. Petitioner opted to use over the counter medication to alleviate pain, but they were not helping. *Id*. at 2-3. Petitioner wrote:

> I discussed my pain, symptoms and problems with my family and finally made the decision to go see my primary care doctor, Dr. Robert Boll once again on February 27, 2012 to discuss the symptoms I had still continue to be experiencing (sic) since receiving the Tdap vaccine at his office.

Id. at 3. Petitioner described seeking treatment with a neurologist and an orthopedist before deciding to treat with Dr. Cleofe. *Id*. at 3-5. She stated that she was diagnosed with "symptoms of frozen shoulder, adhesive capsulitis and shoulder bursitis" and "the MRI also indicated that there was a partial tear and inflammation around the deltoid muscle and/or overlying tendons which could be the cause of tendonitis." *Id*. at 5. None of these conditions were found in the medical records that have been filed.

2. Dr. Boll

Dr. Boll submitted a letter dated May 18, 2017. Pet. Ex. 7 at 1. He stated that petitioner received a Tdap vaccine in his office on February 2, 2012 and over the next 24 to 48 hours, her arm and shoulder near the vaccine site became swollen and painful. *Id*. He stated that she called his office and spoke with a nurse about her symptoms, and over the counter medication and ice were suggested. *Id*. Dr. Boll further stated, "…when [petititioner] saw me for other matters on

February 27, 2012, we discussed the pain she continued to have in her arm." *Id*. At that time, he referred her to a neurologist. *Id*. Dr. Boll noted that he saw petitioner again on June 13, 2012, and she still had shoulder pain. *Id*.

Dr. Boll clarified that, when he wrote this letter, he did not have access to petitioner's records to check the accuracy of the dates referenced. *Id*. The wording of his letter is strikingly similar to the letter submitted by petitioner.

3. David Kreis

Petitioner submitted a letter from Mr. Kreis, a certified athletic trainer and teacher at Carl Sandburg High School, petitioner's former employer, on November 7, 2017. Pet. Ex. 8.2 at 1. Mr. Kreis stated that he recalled petitioner asking for neck and shoulder stretches in mid to late February 2012 due to tight muscles around her shoulder and neck. *Id*. Mr. Kreis stated that petitioner was "having discomfort and soreness while moving her arm and turning her head." *Id*. He showed her three stretches for her neck and three stretches for her arm and shoulder but recommended that she consult her primary care provider or an orthopedic surgeon if her pain persisted. *Id*.

4. Nancy Cassidy

Ms. Cassidy, the school nurse at Carl Sandburg High School, submitted a letter dated April 26, 2017. Pet. Ex. 9 at 1. She recalled that petitioner began working in the nurse's office in 2011 and received a Tdap vaccine in February 2012. *Id*. Ms. Cassidy stated that "immediately" after receiving the Tdap vaccine, petitioner had pain in her left shoulder and upper arm. *Id*. The pain continued and progressed to petitioner's neck and head over the next few weeks, at which time petitioner saw several doctors. *Id*.

5. Florine Martin

Ms. Martin, petitioner's mother, submitted a notarized letter dated November 21, 2017. Pet. Ex. 10 at 1. She recalled that petitioner received the Tdap vaccine on February 2, 2012, because Ms. Martin had recently moved into petitioner's home following the death of Ms. Martin's husband. *Id*. Ms. Martin recalled that petitioner reached out to the doctor's office and spoke to the nurse on duty about her pain. *Id*. The nurse suggested ice and Tylenol or Advil. *Id*. Ms. Martin stated, "Over the next few days, [petitioner] realized that the pain was starting to spread to her neck and shoulder area…". *Id*. Ms. Martin recalled petitioner discussing her arm pain with Ms. Cassidy and one of the personal trainers at school. *Id*. Ms. Martin stated, "After several months had gone by and [petitioner] was not getting any better she finally decided to set up an appointment with a chiropractor…". *Id*.

6. Wayne Clavio

Mr. Clavio, petitioner's husband, submitted a notarized letter dated November 21, 2017. Pet. Ex. 11 at 1. He stated that on the evening of February 2, 2012, after receiving the Tdap vaccination, petitioner mentioned that her arm was hurting. *Id*. Mr. Clavio recalled suggesting that

petitioner speak with the school nurse, Nancy, the next day. *Id*. He recalled that petitioner discussed it with Ms. Cassidy the next day and called Dr. Boll's office "when the pain continued to persist." *Id*. He stated that petitioner's pain progressed over time, and he had to help her with dressing and undressing. *Id*.

7. Yolanda Kolliniatis

Ms. Kolliniatis submitted a notarized letter dated December 2017. Pet. Ex. 12 at 1. She worked with petitioner at Carl Sandburg High School from 2000 to 2014. *Id*. Ms. Kolliniatis recalled that petitioner struggled with pain "immediately after receiving the vaccine." *Id*. Ms. Kolliniatis and petitioner used to spend their lunch breaks together; Ms. Kolliniatis recalled petitioner calling the doctor's office as well as her daughter, a nurse, during their breaks to discuss her pain "for the days and weeks following the immunization." *Id*. Ms. Kolliniates stated, "In spite of attempts with pain medication for relief, the pain quickly progressed and eventually led to decreased motion of her left arm and shoulder." *Id*.

8. Jeannie Murawski

Ms. Murawski submitted a notarized letter dated December 22, 2017; at that time, she was living in Georgia. Pet. Ex. 13 at 1. Ms. Murawski has been friends with petitioner "since the 70s." *Id*. Ms. Murawski recalled that, after petitioner received the Tdap vaccination, she "immediately" had "stiffness and difficulty raising or moving her left arm." *Id*. Ms. Murawski stated, "I believe they told her that depending on where or how the injection was placed in her arm, there might be a problem." *Id*. Ms. Murawski explained that she recalled these details because she was carjacked in March 2012, and "hated to give [petitioner] anything else to be upset or concerned with as I knew she was suffering daily with the pain in her shoulder and left arm." *Id*.

II. Discussion

A. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claims by a preponderance of the evidence. § 13(a)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in an accurate manner, so that they are aware of enough

relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd,* 993 F. 2d. 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred"). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* A patient's motivation for providing an accurate recount of symptoms is more immediate, as opposed to testimony offered after the events in question, which is considered inherently less reliable. *Reusser v. Sec'y of Health & Human Servs*., 28 Fed. Cl. 516, 523 (1993); *see Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948)). Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Cucuras*, 993 F.2d at 1528. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Id.* Similarly, contemporaneous medical records may be considered more persuasive than a petitioner's affidavit created years after the fact. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes).

In order to overcome the presumption of accuracy afford to contemporaneous medical records, witness testimony must be "consistent, clear, cogent and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (quoting *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998)). However, a special master cannot make a finding of fact based on witness testimony alone; the testimony must have some form of corroborating evidence. *See Epstein v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 467, 468 (1996) ("In cases in which a court has based a finding upon lay testimony, there must be corroborating evidence, either medical or otherwise, to support the claim").

B. Determination of Onset

The onset of petitioner's alleged shoulder injury is consistently documented as April of 2012, approximately two months after petitioner received the allegedly causal Tdap vaccine. *See* Pet. Ex. 4 at 9; Pet. Ex. 5 at 10. Petitioner claimed that the onset of her shoulder pain occurred within 48 hours of her Tdap vaccination. Motion at 10. She argued that her medical records are incorrect and submits that the witness statements proffered in support of her claim, combined with a February 11, 2013 record from her chiropractor, Dr. Cleofe, constitute sufficient support for her claim, and should be given greater weight than the records documenting onset of April 2012. *Id*. at 9-10.

Respondent asserted that the contemporaneous medical records consistently place the onset of petitioner's shoulder pain in April 2012 and cannot be overcome by the evidence proffered by petitioner. Response at 1, 8. Respondent pointed out that petitioner did not initially connect her

shoulder pain to the Tdap vaccine and repeatedly "denied any known injury" to her left shoulder to multiple medical providers. *Id*. at 9-10. Respondent further asserted that the witness statements from petitioner's friends and family should be given little evidentiary weight because they are not sworn statements and "do not provide a credible and reliable basis to set aside petitioner's medical records" due to a lack of foundation for the recollections provided therein. *Id*. at 11-13.

In her Reply, petitioner repeated her assertion that Dr. Cleofe's record corroborates her claim and should be given great weight. Reply at 3. She cites a fact ruling on a SIRVA claim, *Tenneson v. Sec'y of Health & Human Servs*., No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. March 30, 2018), submitting that the facts are sufficiently similar to the instant matter so as to dictate a ruling in petitioner's favor. Reply at 4-6. Petitioner further submitted that her denials of "any known injury" should be disregarded, as she would not identify a vaccination as an "injury." *Id*. at 6-7. Additionally, petitioner appeared to argue that respondent has waived his right to dispute the facts pertaining to onset, stating"[i]f respondent wishes to challenge Dr. Boll's recollection as to whether these events happened, otherwise challenge the recollection of any of the other fact witnesses . . . he should insist on the opportunity to cross examine them under oath . . . [otherwise] the Special Master should accept their fact statements/affidavits as true." Reply at 8-9.

For the reasons outlined below, I find that the onset of petitioner's left shoulder pain was in April 2012.

1. The contemporaneous medical records support an onset in April 2012

Petitioner "urge[d] the Special Master to give greater weight to the statements of the petition and the seven other declarants affiants (sic) than to the omission of onset information in the medical records." Motion at 9. In support of her position, petitioner submitted that there is a missing record of a telephone call to Dr. Boll made between 24 and 48 hours of vaccination and missing information from an appointment on February 27, 2012.

Petitioner stated that, within 24 to 48 hours of receiving the Tdap vaccination, she called Dr. Boll's office to complain of shoulder pain and spoke to a nurse, who recommended ice and over the counter medication. Pet. Ex. 8 at 1. None of the medical records from Dr. Boll's office reflect such a call. According to petitioner, "it is not clear whether the office even maintained records of telephone calls from patients." Motion at 5. Dr. Boll submitted a statement reiterating that petitioner called and spoke to a nurse. Pet. Ex. 7 at 1. He did not address whether telephone calls from patients were routinely documented. Several of petitioner's other witnesses, including Ms. Kolliniatis, Ms. Murawski, Ms. Martin, and Mr. Clavio, state that petitioner called Dr. Boll's office about her shoulder pain. *See* Pet. Ex. 10 at 1 (Petitioner's mother stated, "As the hours passed and the pain was increasing I do recall that Maureen had reached out to her doctor's office and had complained to the nurse on duty of the pain she was feeling."); Pet. Ex. 11 at 1 (Petitioner's husband stated, "The next day Maureen…called Dr. Boll's office when the pain continued to persist."); Pet. Ex. 12 at 1 (Petitioner's co-worker recalled "several calls during our lunch breaks immediately after the vaccine was given to both her doctor's office and to her daughter…"); Pet. Ex. 13 at 1 (Petitioner's friend stated, "I know that she contacted her Physician [sic] right away to ask if these symptoms might have something to do with the TDAP injection."). The statements

submitted by Dr. Boll and petitioner's other witnesses were made years after the telephone call in question. Neither Dr. Boll nor petitioner's friends or family noted having witnessed this telephone call, but rather were told that it happened after the fact.

In his statement, Dr. Boll recalled that he and petitioner discussed her arm pain at an appointment on February 27, 2012, even though this is not reflected in the record for this appointment, but his record does reflect complaints of pain in her ear and the left side of her face. Petitioner submits that, per *Murphy v. Sec'y of Health & Human Servs*., this correction by Dr. Boll should be considered persuasive. 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992) ("If a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account."). However, the records indicate that on this date, petitioner was seen by a nurse practitioner, Maya Karam, not Dr. Boll. As Dr. Boll himself admitted, he did not review petitioner's medical records to check the accuracy of his dates. It seems more likely that Dr. Boll based his letter on facts relayed to him by petitioner. It strains reason that Dr. Boll, a primary care physician who undoubtedly conducts hundreds of patient office visits per year, would remember a specific visit with petitioner four years later, particularly without consulting medical records, especially since the doctor did not see the patient on that date.

Respondent submitted that petitioner gave no explanation as to why all of her medical records reflect an onset of shoulder pain in April 2012, yet argues that all of her records are incorrect, "which lacks credibility, as at least three different doctors all reported the same onset date of April 2012 in their records based on petitioner's contemporaneous statements." Response at 11, citing Pet. Ex. 4 at 9, 32; Pet. Ex. 2 at 4.

To further support his assertion that petitioner's medical records support an onset of shoulder pain in April 2012, respondent pointed out "petitioner states that she also developed jaw pain when her left shoulder symptoms began, and her dental records note that she first sought care for that condition in May 2012." Response at 10, citing Pet. Ex. 6 at 1. Petitioner echoed this statement during an appointment with Dr. Cleofe on April 22, 2013, when she reported that her jaw pain began in April 2012, around the same time as her left shoulder pain. *See* Pet. Ex. 3 at 53.

Respondent also cited to petitioner's visit with Dr. Boll on June 13, 2012, where petitioner denied sustaining any injury, and an appointment with Dr. Regan on June 18, 2012, where petitioner stated that her left shoulder pain had a "spontaneous onset." Pet. Ex. 4 at 9 (Petitioner's chief complaint listed as "c/o pain to L UE radiating to L lat neck/L temporal area x2 months, denies injury"); Pet. Ex. 2 at 3 ("She is having trouble with her left temple and down into her shoulder. She has been treating this conservatively with spontaneous onset.").

Petitioner responded that she would not have identified a vaccination as an "injury." Reply at 6. In petitioner's interpretation, "injury…most likely means falling off a bike or accidentally getting hit with a golf club, not the administration of a vaccine…" *Id*. at 7. However, if petitioner had experienced shoulder pain within 24 to 48 hours of vaccination, then it would be expected that she would connect that shoulder pain to the vaccine, even if she would typically not identify it as an "injury."

2. Dr. Cleofe's record does not support an onset in February 2012

Petitioner relied heavily on a record from an appointment with Dr. Cleofe, a chiropractor, on February 11, 2013, when she presented with chronic left shoulder pain to support her claim of onset in February 2012. Motion at 3; Pet. Ex. 3 at 1. Petitioner submitted that Dr. Cleofe "found a possible precipitating cause was 'TDAP injection in April 2012?'[sic]." Motion at 3, citing Pet. Ex. 3 at 1. Petitioner asserted, "This record clearly associates the onset of petitioner's pain with her vaccination although it admittedly does not tell exactly when that pain began." Reply at 3. Petitioner then clarified that, in another part of the record, "Dr. Cleofe specifically noted, "she cannot report any other specific trigger factor for the pain except that she had a TDAP Shot in her L shoulder 1 day prior to all the pain starting." *Id*., citing Pet. Ex. 3 at 1 (emphasis omitted). Petitioner concluded, "The two references in Dr. Cleofe's record of February 11, 2013, especially when read together, provide clear and convincing medical record corroboration for petitioner's affidavit and the statements of the other seven declarants." *Id*. Petitioner further asserted that Dr. Cleofe's record from February 2013 should be given "great weight" because it "was not created for purposes of litigation, nor at a time when SIRVA was a known injury." *Id*.

When examined in further detail, Dr. Cleofe's record does not support an onset of shoulder pain in February 2012. Dr. Cleofe did not examine petitioner until a year after her Tdap vaccination, approximately eight months after her first documented complaint of shoulder pain. At this appointment, petitioner initially reported that in April 2012, she woke up with pain in her left temple and later noticed it in her left arm and neck. *See* Pet. Ex. 3 at 11. She did not connect her shoulder pain with the Tdap vaccine until Dr. Cleofe asked her about any possible precipitating events. *Id*. at 2, 11. She then provided an inaccurate history, stating that she received a Tdap vaccine in April 2012, rather than February. Petitioner's consistent reporting of shoulder onset in April of 2012 is telling.

3. The witness statements proffered by petitioner lack foundation

Respondent submitted that the witness statements offered by petitioner should be given little weight because they are unsworn and do not "contain the required language for statements given under oath." Response at 11. While respondent is correct that the witness statements do not meet the criteria articulated in 28 U.S.C. § 1746, the Vaccine Program was designed to have "flexible and informal standards of admissibility of evidence." 42 U.S.C. § 300aa-12(d)(2)(B); *see also Munn v. Sec'y of Health & Human Servs*., 970 F.2d 863, 873 (Fed. Cir. 1992) (finding that the Federal Rules of Evidence are inapplicable in Vaccine Act proceedings); *Stevens v. Sec'y of Health & Human Servs*., 31 Fed. Cl. 12, 20-21 (1994) (special master correctly concluded that the Federal Rules of Civil Procedure do not apply to proceedings under the Vaccine Act). It would be counterpoint to these purposefully relaxed standards to require witness statements to meet the statutory requirement for unsworn statements in order to be given any significant evidentiary weight.

However, respondent correctly pointed out that most of petitioner's witnesses do not provide a foundation for the basis of their recollections. Response at 12-13. Petitioner submitted that Florine Martin and Jeannine Murawski connected their memories to significant life events.

Ms. Martin stated that she recalled the onset of petitioner's injury because Ms. Martin's husband "had recently passed away" and Ms. Martin had moved in with petitioner. However, Ms. Martin did not provide any specific dates for when her husband passed or when she moved in with petitioner. Ms. Murawski stated that she recalled the onset of petitioner's injury because she was the victim of a carjacking in March of 2012 and did not want to burden petitioner with this news due to her shoulder injury.

"It is the court's experience that people tend to recall events in connection with holidays or days of special significance such as birthdays or anniversaries. In fact, a recollection tied to such an event often lends credibility to the particular remembrance." *O'Leary v. Sec'y of Health & Human Servs.*, 1998 WL 218224 at *8 (Fed. Cl. Spec. Mstr. Apr. 17, 1998). While Ms. Murawski provided a significant event and specified the month in which it occurred, Ms. Martin did not provide the time frame in which her husband's death occurred. Conversely, Dr. Mayer noted during petitioner's appointment on June 29, 2012, that petitioner specifically connected the onset of her pain "around Easter time in April" Pet. Ex. 4 at 32. Respondent noted that, in 2012, Easter fell on April 8. Response at 3, n.1. Petitioner's consistent reporting to various unrelated medical providers that the onset of her left shoulder pain was in April around Easter lends credence to the significance of holidays and memory.

4. *Tenneson* is distinguishable from the instant matter

Petitioner cited to *Tenneson v. Sec'y of Health & Human Servs*., No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. March 30, 2018) for support. In *Tenneson*, the first documentation of Ms. Tenneson's shoulder pain occurred approximately six months after she received the allegedly causal vaccination. *Id.* at *5. During the six-month period between vaccination and documentation of shoulder pain, Ms. Tenneson had presented to the emergency room for kidney stones and had not complained of shoulder pain. *Id.* The special master found that Ms. Tenneson had an onset of shoulder pain within 48 hours of vaccination based on affidavits from Ms. Tenneson, her husband, and her son, combined with medical records indicating that, when Ms. Tenneson did seek medical care for her shoulder pain, she reported that she had had arm pain since the flu shot. *Id.* at *5-6. She gave the same history to a physical therapist the following month. The special master found that Ms. Tenneson "repeatedly and consistently placed the onset of her condition within 48 hours of vaccination." *Tenneson* at *5.

Upon review, the Court of Federal Claims affirmed the special master's decision, noting that the special master cited to medical records in which petitioner consistently placed the onset of her shoulder pain directly after the vaccination. *Tenneson v. Sec'y of Health & Human Servs.*, 142 Fed. Cl. 329, 338 (2019). The Court of Federal Claims agreed with the special master's finding that the emergency room where petitioner did not mention her shoulder pain was not disqualifying; the Court noted, "After all, the purpose of an emergency room visit is to receive emergency treatment, not a comprehensive health check-up." *Id*. at 340.

The instant matter is distinguishable from *Tenneson*. In *Tenneson*, the medical visit that occurred between vaccination and the petitioner's first documented report of shoulder pain was an emergency room visit for kidney stones. It was reasonable that the petitioner did not report her shoulder pain when the purpose of her visit to the emergency room was to receive treatment for

kidney stones and her debilitating condition. Here, petitioner received the Tdap vaccination on February 2, 2012, from her primary care provider; on February 27, 2012, she returned to her primary care practice with complaints of nasal congestion, sore throat, non-productive cough, ear pain, and pain on the left side of her face and teeth. Petitioner did not report left shoulder pain at this appointment.

Petitioner submitted that her situation is similar to *Tenneson* because she presented to her primary care practice for an acute illness, noting that she was diagnosed with sinusitis and prescribed an antibiotic. Motion at 7. Unlike *Tenneson*, however, petitioner returned to the doctor who administered the vaccine and reported sinusitis and pain in her ear and left side of her face. It follows that someone returning to the doctor who administered an allegedly causal vaccine in a non-emergent situation would be more likely to mention shoulder pain, if it existed, than someone in Ms. Tenneson's position. Accordingly, it appears petitioner would have mentioned her shoulder pain, if it had been present, at her February 27, 2012 visit. Her failure to mention any such pain bolsters the conclusion that onset of her pain began in April of 2012.

5. Petitioner must prove onset by a preponderance of the evidence

In submitting that respondent must request cross-examination of witnesses in order to challenge the reliability of their statements, petitioner incorrectly placed the burden on respondent to disprove petitioner's proffered facts, when it is petitioner's burden to prove the factual circumstances surrounding her claim by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1)(A); *see also* 42 U.S.C. § 300aa-13(b)(2) ("[t]e special master or court may find the first symptom or manifestation of onset…occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset…did in fact occur within the time period described in the Vaccine Injury Table.").

Petitioner further stated that she "is happy to provide the statements in the form of sworn affidavits if the Special Master indicates that his is an important consideration. Alternatively, the Special Master can conduct a fact hearing and the witnesses can testify under oath." Reply at 7. Petitioner had the opportunity to request a fact hearing and instead chose to pursue a factual ruling based on the record. It is inappropriate for petitioner to imply that she would have chosen to proceed to a hearing, if only she had known that respondent would question the reliability of her witnesses. If respondent agreed with petitioner that her witnesses were reliable and accurate historians, then respondent would not have questioned onset but would have instead accepted the proffered witness statements as persuasive evidence.

6. Onset occurred in April 2012

Petitioner's affidavit and witness statements are insufficient to overcome the presumption of accuracy afforded to contemporaneous medical records. Petitioner's medical records indicate that she was vigilant about her health; she had yearly bloodwork done at her place of employment, which she then faxed to Dr. Boll and requested follow-up calls to discuss her results. When she was sick or had pain, she went to the doctor. This is evidenced by the records of the treatment she

sought for her left hip and left knee pain. Once petitioner began seeking treatment for her left shoulder pain, she consistently presented for care with multiple physicians, physical therapy, and then chiropractic care as many as three times per week. Based on the contemporaneous medical records, the onset for petitioner's left shoulder pain appears to be April 2012, based on petitioner's presentation to Dr. Boll on June 13, 2012, when she reported left shoulder pain for two months. Onset in April 2012 is supported by petitioner's report to Dr. Mayer that her shoulder pain began around Easter, which was on April 8 that year, and by petitioner's report to Dr. Cleofe that her jaw pain began in April 2012, around the same time as her left shoulder pain.

III. Conclusion

Upon detailed review of the record, I find that petitioner's left shoulder pain began in April of 2012. Petitioner has 30 days to submit a status report indicating how she intends to proceed.

Accordingly, the following is ORDERED:

Petitioner's status report is due **by no later than Friday, April 10, 2020.**

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master